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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,712	10/27/2003	Hideki Taniguchi	25682	2281

20529 7590 06/28/2006

NATH & ASSOCIATES
112 South West Street
Alexandria, VA 22314

EXAMINER

POPA, ILEANA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/693,712	Applicant(s) TANIGUCHI ET AL.	
	Examiner Ileana Popa	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claim 1-74 are pending.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13, 18-21, 25-31, 38-48, 51, 52, and 56, drawn to a method of separating a pancreatic stem cell from the pancreas of a mammal, classified in class 435, subclass 7.2.
 - II. Claims 15, and 49, drawn to a method of screening a substance that induces differentiation of a pancreatic stem cell into liver/bile duct, or stomach/intestine, classified in class 435, subclass 375.
 - III. Claims 14, 16, 17, and 50, drawn to a method of screening a substance that regulates of a pancreatic cell function of a mammal, classified in class 435, subclass 375.
 - IV. Claims 22-24 and 53-55, drawn to a method of transplanting a cloned pluripotent pancreatic stem cell into a host, classified in class 424, subclass 93.1.
 - V. Claims 32, 33 and 57-62, drawn to an agent for the prophylaxis or treatment of a pancreatic hypofunctional disease, classified in class 424, subclass 93.1.

- VI. Claims 34, 35, and 63-68, drawn to an agent for the prophylaxis or treatment of a hypofunctional disease of the liver or bile duct, classified in class 424, subclass 93.1.
- VII. Claims 36, 37, and 69-74, drawn to an agent for the prophylaxis or treatment of a hypofunctional disease of the stomach or intestine, classified in class 424, subclass 93.1.

3. It is noted that the inventions of Groups V-VII are drawn to an agent for the prophylaxis or the treatment of the disease. Such language directed to a therapeutic agent is considered to directly embrace administering to animals a therapeutic agent in an amount sufficient such that the treatment of an animal having a condition associated with the therapeutic agent is achieved, and therefore the inventions of Groups V-VII are considered to be drawn to a method for the prophylaxis or the treatment of a disease associated with the claimed agent.

The inventions of Groups I-VII are patentably distinct because they are drawn to methods that require different compositions and different steps for practice and also result in different outcomes. For example, steps and compositions for isolating a pancreatic stem cell, transplantations, screening for substances that induce differentiation of a pancreatic stem cell into liver/bile or stomach/intestine, screening for a substance that regulates a pancreatic function, or for prophylaxis or treatment of a disease are all distinct from each other. Moreover, the outcomes of the methods are

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distinct from each other. For example, the method of Group I results in the isolation of pancreatic stem cells, the method of Groups II and III result in the identification of a substance that induces differentiation of a pancreatic stem cell or that regulates a function of a pancreatic cell, respectively, whereas the methods of Groups IV-VII result in the treatment or the prophylaxis of distinct diseases. Therefore, these distinct inventions require separate searches in the patent and non-patent literature, and examination of anything more than one of the above-designated inventions would be a burden for the Examiner.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

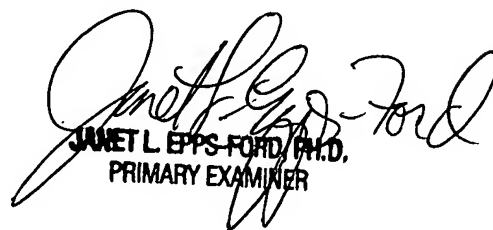
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa



JANET L. EPPS-FORD, Ph.D.
PRIMARY EXAMINER